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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,401	11/10/2003	Henrik Clausen	04305/100H154-US2	4414
7278	7590	06/13/2006	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257				FRONDA, CHRISTIAN L
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/705,401	CLAUSEN ET AL.
	Examiner Christian L. Fronda	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is FINAL.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-40 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) 1-40 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____.
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## **DETAILED ACTION**

### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim(s) 1-4, 9-11, drawn to an isolated nucleic acid molecule and method of producing a lectin polypeptide, classified in class 435, subclass 69.1.
  - II. Claim(s) 5-8, drawn to an isolated lectin polypeptide, classified in class 530, subclass 350.
  - III. Claim(s) 12, drawn to a method of identifying a substance that binds to a polypeptide GalNAc-transferase lectin domain, classified in class 435, subclass 7.1.
  - IV. Claim(s) 13, drawn to a method of screening for inhibitors of functions mediated by polypeptide GalNAc-transferase lectin domains comprising using a lectin polypeptide in a binding assay, classified in class 435, subclass 7.71.
  - V. Claim(s) 14, drawn to a method of screening for inhibitors of functions mediated by polypeptide GalNAc-transferase lectin domains comprising using a polypeptide GalNAc-transferase or fragment thereof retaining functional lectin binding in a binding assay where it interacts with a GalNAc or Gal $\beta$ 1-3GalNAc O-glycopeptide ligand or molecular mimic thereof, classified in class 435, subclass 7.71.
  - VI. Claim(s) 15, 16, drawn to a compound that binds to the lectin domain of a member of the mammalian family of polypeptide GalNAc-transferases, classified in class 530, subclass 350.
  - VII. Claim(s) 17-21, drawn to an inhibitor of polypeptide GalNAc-transferase lectin-mediated functions, classified in class 435, subclass 69.2.
  - VIII. Claim(s) 22, 35, drawn to a method of inhibiting mucin secretion in a subject comprising administering an effective amount of a compound that binds to one or more lectin domains of members of mammalian family of polypeptide GalNAc-transferases, classified in class 514, subclass 8.
  - IX. Claim(s) 23-25, 36, 37, drawn to a method of inhibiting hypersecretion and accumulation of mucin in the lungs of a mammal suffering from a chronic obstructive respiratory pulmonary disease, classified in class 514, subclass 8.

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- X Claim(s) 26-28, drawn to a method of inhibiting the secretion in a patient comprising administering GalNAc $\beta$ 1-benzyl, classified in class 514, subclass 8.
- XI. Claim(s) 29-32, drawn to a method of modulating the function of one or more lectin domains of a polypeptide GalNAc-transferase comprising administering an effective amount of GalNAc  $\beta$ 1-R, classified in class 514, subclass 8.
- XII. Claim(s) 33, drawn to a method of screening one or more test substances for the ability to inhibit or modulate intracellular transport and/or cell surface of mucins, classified in class 435, subclass 7.2.
- XIII. Claim(s) 34, 38, drawn to a method of screening one or more test substances for the ability to inhibit or modulate secretions of mucins, classified in class 435, subclass 7.1.
- XIV. Claim(s) 39, 40, drawn to a method of inhibiting mucin secretion in a cell comprising delivering to a cell an effective amount of a compound that binds to one or more lectin domains of members of a mammalian family of polypeptide GalNAc-transferases, classified in 514, subclass 8.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I, II, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each of the products of Groups I, II, VI, and VII are different and independent products and require different literature searches.

Inventions of Groups III-V, VIII-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The processes of Groups III-V, VIII-XIV are patentably distinct because they require different process steps, reagents, and parameters, and have different purposes.

Inventions of Groups XII-XIV are unrelated to inventions of Groups I, II, VI, and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each of the processes of Groups XII-XIV does not require the products of Groups I, II, VI, and VII.

Inventions of Groups III-V are unrelated to inventions of Groups VI and VII. Inventions

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are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each of the processes of Groups III-V does not require the products of Groups VI and VII.

Inventions of Groups VIII-XI are unrelated to inventions of Groups I and II. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each of the processes of Groups VIII-XI does not require the products of Groups I and II.

Invention of Groups VIII is unrelated to invention of Group VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The process of Group VIII does not require the product of Group VII.

Inventions of Groups IX-XI are unrelated to invention of Group VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The processes of Group IX-XI do not require the product of Group VI.

Group V and Groups (III-V) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as using the polypeptide in a process to make antibodies to the polypeptide.

Group VI and Group VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as using the compound in a chromatography process to purify and isolate a polypeptide GaINAc-transferase.

Group VII and Groups IX-XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as using the inhibitor in a chromatography process to purify

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and isolate a polypeptide GalNAc-transferase.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and classification, restriction for examination purposes as indicated is proper.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

**Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to

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reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

6. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

  
TEKCHAND SAIDHA  
PRIMARY EXAMINER